UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,523	10/14/2005	Yoshiharu Uehata	10921.362USWO	1562

52835 7590 11/19/2009

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER	
EASTWOOD, DAVID C	

ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
11/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,523	UEHATA ET AL.	
	Examiner	Art Unit	
	DAVID EASTWOOD	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/27/2009 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1-8 and 19-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Garthe et al (US 2003/0225429 henceforth referred to as Garthe).

Regarding claims 1-8 and 19-21 Garthe discloses a lancet holder (lancet holding tray depicted in figure 1) for retaining a lancet, the lancet including a main body (11) and a needle (30') projecting from the body, the lancet holder being moved in a lancing direction from a standby position to a lancing position together with the lancet so as to cause the lancet to stick into an object (progression of fig. 4 a-c), the lancet (capable of) being inserted into the lancet holder in a retreating direction opposite to the lancing direction, thus to be retained by the lancet holder (fig. 4a), wherein the lancet holder

includes a first member (60) and a second member (40) that are movable relative to each other(progression of fig. 4 a-b), the second member being movable relative to the first member between a fixing position (retracted position in figure 4a) in which the main body of the lancet is fixed to the lancet holder with a first fixing force (fixing force provided via fixing mechanism 53) and a non-fixing position (fig. 4b) in which the main body of the lancet is held by the lancet holder with a second fixing force (via second fixing mechanism 52) smaller than the first fixing force (the first fixing mechanism has a larger gradient than the second thus the first fixing force would be greater than the second) for facilitated removal from the lancet holder (via deflection of second member arms at the proximal end of 40), at least either of the first and the second members applies a pressing force to the lancet for fixing the lancet (via cam fixing mechanisms 52,53), when loading the lancet, the lancet moves relative to the first member, while the second member moves together with the lancet relative to the first member in the retreating direction from the non-fixing position toward the fixing position (progression of fig. 4 a-c), and wherein the lancet holder applies a greater pressing force to the lancet when the second member is located at the fixing position than when the second member is at the non-fixing position (progression of fig. 4 a-c), further comprising fixing means (61,53 and 41,52) that applies a pressing force to the lancet for fixing the lancet when the second member is at the fixing position (progression of fig. 4 a-c), the first and the second members respectively include a first engaging portion (41) and a second engaging portion (annular wall within fixing mechanism 52) that are engaged with each other when the second member is at the fixing position, the fixing means comprising the

first and second engaging portions (fig. 4a), wherein at least one of the first and the second engaging portions projects toward the other of the first and the second engaging portions (Fig. 4a), one of the first and the second engaging portions comprises a recess (groove within 52), and the other of the first and the second engaging portions comprises a projection (projecting portion of 41) to be fitted into the recess. The first member (60) includes a pressing portion (51) that applies a pressing force to the lancet (via rotation of item 51 producing a rotation of the second fixing mechanism 52 applying a force to the lancet needle) and wherein the second member includes a working portion (weighted portion of 60) that displaces at least a part of the pressing portion from the lancet when the second member is located at the non-fixing position or between the non-fixing position and the fixing position (via motion of the weighted component of second member 60), a pushing member (distal end of 51 near fixing mechanism 52) that moves the second member in the lancing direction, the pushing member (51) includes a working portion (annular walls of groove 52) that interferes with the second member and an operating portion to be manipulated so as to move the working portion (progression of fig 4 a-c), the second member (40) including a movable fixing portion (52) that moves in a direction crossing the needle extending direction for fixing contact with the main body of the lancet in response to the movement of the second member from the non-fixing position to the fixing position (progression of fig. 4a-c).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 9, 16, 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe (US 2003/0225429) in view of Kageyama et al. (US 6,039,485, henceforth referred as Kageyama).

Garthe discloses the apparatus substantially as claimed but fails to disclose a pair of movable portions wherein a gap is provided between the moving portions. Although Garthe fails to explicitly disclose a portion for engaging a lancet, one having

ordinary skill in the art would recognize that such a portion would be provide since the device is capable of moving without the lance held therein being dislodged from it.

Kageyama discloses a dispenser comprising members movable relative to each other (figure 10 and12 (34), (26)) that apply pressing force to holds a lead in between (column 1, lines 36-45) for advancing and retracting the lead. Although this invention is used to hold the lead, however this holding mechanism of Kageyama's invention is capable of holding a lancet and advancing and retracting the lancet. The holder applies greater pressing force due to the movement of relative moving members. The holding space between holding members decreases as they moves relative to each other, which results in pressing and holding, as it said, "The size of the gap "d" further decreases to reliably tighten the lead when the tip chuck 34 moves backward to its rear-most position, into the tip fitting 12" (column 10, lines 20-22).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's apparatus by providing a holding mechanism as taught by Kageyama so as to enhance the lancet holder's ability to firmly hold the lancet when moving it back and forth.

Concerning claims 16 and 17, Kageyama discloses an invention comprises of two movable members. The gap between these members changes as they move relative to each other (column 10, lines 20-24). The distance between these two members decreases when one member moves in retreating direction with respect to other member (column 10, line 20) and vice versa.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Garthe's apparatus by providing a lancet-holding mechanism as taught by Kageyama so as to obtain efficient loading and unloading of the lancet.

3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe (US 2003/0225429) in view of Kageyama (US 6,039,485) as applied to claim 9 above, and further in view of Okumura et al. (US 6,226,873, henceforth referred to as Okumura).

The Garthe and Kageyama combination discloses the apparatus substantially as claimed but fails to disclose that lancet holding mechanism contains cutaway portions.

Okumura discloses an apparatus comprising of movable portions, which includes cutaway (figure 1, (lb)). The working portion fits into the cutaway (figure 1 and column 1, lines 52-62).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of the Garthe and Kageyama combination by providing a cutaway portion as taught by Okumura in order to improve the device's locking capability.

4. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe in view of Kageyama (US 6,039,485) and Okumura (US 6,226,873) as applied to claim 10 above, and further in view of Searle et al (US 2002/0087180, henceforth referred to as Searle).

The Garthe, Kageyama and Okumura combination discloses the apparatus substantially as claimed but fails to disclose a cutaway comprising a first cutaway portion into which a working portion is fitted.

Searle discloses an invention, which contains first cutaway portion into which working portion (figure 7, (26), (46)) is fitted in fixing the lancet (figure7) and second cutaway portion into which working portion is fitted in discharging the lancet (figure 9).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of the Garthe, Kageyama and Okumura combination by providing a cutaway portion as taught by Searle so as to have better control in locking the lancet.

5. Claims 12, 13, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garthe in view of Kageyama (US 6,039,485) and Okumura (US 6,226,873) as applied to claim 10 above, and further in view of Ritson et al. (US 5,041,088, henceforth referred to as Ritson).

The Garthe, Kageyama and Okumura combination discloses the apparatus substantially as claimed but fails to disclose a cutaway portion arranged to make a gap continuously or incrementally narrower.

Ritson discloses a lancing apparatus that contains a stepped portion for change in gap (column 4, lines 36-43).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of the Garthe, Kageyama and Okumura combination

by providing a step portion for change in the diameter of holding mechanism as taught by Ritson so as to have rapid fixation of the lancet.

Response to Arguments

Applicant's arguments filed 8/27/2009 have been fully considered but they are not persuasive. Applicant states Garthe fails to disclose a lancet holder that includes a first member and a second member, where the second member is movable relative to the first member between a fixing position in which a main body of a lancet is fixed to the lancet holder with a first fixing force and a non-fixing position in which the main body of the lancet is held by the lancet holder with a second fixing force smaller than the first fixing force for facilitated removal from the lancet holder. The examiner respectfully disagrees. As can be clearly seen in the preceding office action Garthe discloses a lancet holder (lancet holding tray depicted in figure 1) that includes a first member (60) and a second member(40), where the second member is movable relative to the first member between a fixing position in which a main body of a lancet is fixed to the lancet holder with a first fixing force and a non-fixing position in which the main body of the lancet is held by the lancet holder with a second fixing force (progression of figures 4 a-c) smaller than the first fixing force (the first fixing mechanism has a larger gradient than the second thus the first fixing force would be greater than the second) for facilitated removal from the lancet holder (via deflection of second member arms at the proximal end of 40). Applicant goes on to argue that the relative positioning between the first member 60 and the second member 40 in Garthe et al. does not appear to affect the

removability of the lancet 30' from the lancet holder. The examiner again respectfully disagrees. As can be clearly seen in figure 4c relative motion of first and second members (40 and 60 respectively) places the members a greater distance apart providing space for a user to dislodge the second fixing mechanism (41,52) and remove the lancet needle (30).

In response to Applicant's argument that Kageyama (US 6039485) is nonanalogous art, it has been held that the determination that a reference is from a nonanalogous art is twofold. First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved (In re Wood, 202 USPQ 171, 174.). In this case although this invention is used to hold the lead, however this holding mechanism of Kageyama's invention is capable of holding a lancet and advancing and retracting the lancet. The holder applies greater pressing force due to the movement of relative moving members. The holding space between holding members decreases as they move relative to one another, which results in pressing and holding, as it said, "The size of the gap "d" further decreases to reliably tighten the lead when the tip chuck 34 moves backward to its rear-most position, into the tip fitting 12" (column 10, lines 20-22).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID EASTWOOD whose telephone number is

(571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID EASTWOOD/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
11/18/09